Election/Restrictions

Claims 2-5, 15 and 20-29, as amended by the examiner's amendment below, are allowable. The restriction requirement between Groups 1 and III (the restriction requirement between Groups I and III was withdrawn in the Office action mailed 1/20/2011) and V, as set forth in the Office action mailed on 10/13/2010, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement is hereby withdrawn as to any claim that requires all the limitations of an allowable claim.** Claim 41, 52, 56-59 and 61-67, directed to administering and EPIP and erythropoietin to a subject are no longer withdrawn from consideration because the claim(s), as amended by the examiner's amendment below, require all the limitations of an allowable claim. However, claims 40, 72-78, 81-84 and 98-101, remain withdrawn from consideration because they do not all require all the limitations of an allowable claim.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Scott Marty on 7/28/2011.

The application has been amended as follows:

IN THE TITLE:

The title has been replaced by the following:

-- Compositions and Methods Related to Erythropoietin --.

IN THE SPECFICATION:

On page 1, lines 1-3 have been replaced by the following:

-- This application is a national stage entry of PCT/US04/11003, filed 4/9/2004, which claims priority to U.S. provisional application 60/461,941, filed 4/9/2003, which is incorporated herein in its entirety by reference. --

It is noted that the amendment to the specification filed 5/17/2011 was made to the published application and not the specification as filed. The following amendments have been made to the specification as filed.

On p. 6, line 1 was replaced by the following:

-- Figures 21A and 21B show that the cells are resident fibroblasts. Having excluded the --.

On page 6, line 11 was replaced by the following:

-- Figures 22A and 22 B show two more profiles of CD73 positive interstitial cells in poly-D- --.

On page 6, line 27 was replaced by the following:

-- Figures 27 A-D show localization of erythropoietin mRNA in peritubular interstitial --.

IN THE ABSTRACT:

The abstract has been replaced by the following:

-- Disclosed are methods and compositions related to the production of erythropoietin. The disclosed compositions comprise a poly amino acid. The production of erythropoietin by the disclosed compositions and methods can take place *in vivo,* in which the proliferation of a subject's erythropoietin-producing cells leads to an increased level of production of erythropoietin, *in vitro,* in which increased proliferation of cultured erythropoietin-producing cells leads to an increased production of erythropoietin, *ex vivo,* in which cells or tissues harvested from a subject produce erythropoietin. The disclosed compositions can be administered to a subject or applied to cells or tissues to stimulate increased production of erythropoietin. The disclosed compositions and methods can be used, for example, to treat anemia, such as anemia associated with diseases and disorders such as chronic renal failure, end stage renal disease, malignancies, HIV infections and AIDS, rheumatoid arthritis, myeloma, and myeloplastic syndrome, and other diseases and disorders. --

IN THE CLAIMS:

Claims 1, 19, 40, 56, 58, 59, 72-78, 81-84, 98-101 and 104 have been cancelled.

Claims 2-5 have been replaced by the following:

-- 2. A pharmaceutical composition comprising an erythropoietin production inducing peptide (EPIP), wherein the EPIP is selected from the group consisting of poly-D-glutamic acid, poly-L-glutamic acid, poly-D-aspartic acid and poly-L-aspartic acid; erythropoietin; and

a pharmaceutically acceptable diluent, adjuvant or carrier.

3. The pharmaceutical composition of claim 2, comprising a therapeutically effective amount each of the erythropoietin and the EPIP.

4. The pharmaceutical composition of claim 2, comprising a therapeutically effective amount of the EPIP.

5. The pharmaceutical composition of claim 2, wherein the erythropoietin is recombinant. --

In claims 15, 20 and 22-25, in line 1 of each claim “The composition” was replaced by -- The pharmaceutical composition --.

Claim 21 has been replaced by the following:

-- 21. The pharmaceutical composition of claim 2, further comprising a buffering agent. –

Claims 27-29 have been replaced by the following:

-- 26. The pharmaceutical composition of claim 2, wherein the pharmaceutical composition is an aqueous solution, a non-aqueous suspension, or a dry powder.

27. The pharmaceutical composition of claim 2, wherein the pharmaceutical composition is in an oral dosage form.

28. The pharmaceutical composition of claim 2, further comprising a fatty acid, a surfactant, enteric material, or a mixture thereof.

29. The pharmaceutical composition of claim 2, wherein the pharmaceutical composition is an in an injectable form. –

Claim 41 has been replaced by the following:

-- 41. A method for treating a condition selected from the group consisting of anemia, Crohn's Disease, ulcerative colitis, chronic renal insufficiency, end stage renal disease and wound healing, comprising:

administering a therapeutically effective amount a pharmaceutical composition comprising an erythropoietin production inducing peptide (EPIP), wherein the EPIP is selected from the group consisting of poly-D-glutamic acid, poly-L-glutamic acid, poly-D-aspartic acid and poly-L-aspartic acid;

erythropoietin; and

a pharmaceutically acceptable diluent, adjuvant or carrier, to a subject in need thereof.

–

Claim 52 has been replaced by the following:

-- 52. The method of claim 41, wherein the EPIP is poly-D-glutamic acid. –

Claim 57 has been replaced by the following:

-- 57. The method of claim 41, wherein the method of treatment results in angiogenesis of a kidney of the subject. --

Claims 63-67 have been replaced by the following:

-- 63. The method of claim 41, wherein the pharmaceutical composition is

administered by intravenous or intramuscular or subcutaneous or intraperitoneal injection.

64. The method of claim 41, wherein pharmaceutical composition is administered orally or rectally.

65. The method of claim 41, the pharmaceutical composition is administered by inhalant.

66. The method of claim 65, wherein the administration by inhalant is via a spraying or droplet mechanism.

67. The method of claim 52, wherein the administration of the poly-D-glutamic acid results in a red blood cell level of 5000 or more erythrocytes per μL of blood. –

The following is an examiner's statement of reasons for allowance: The limitations for claims 65 and 66 are supported by the specification at page 34, lines 18-21.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sue Liu can be reached on 571-272-5539. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Primary Examiner, Art Unit 1653